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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,336	08/29/2001	Tetsuo Ashizawa	HO-P02039US1	7107

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EXAMINER

HASHEMI, SHAR S

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 07/03/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/942,336

Applicant(s)

ASHIZAWA ET AL.

Examiner

Shar Hashemi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 18-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☒ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-17, are drawn to methods of measuring DNA expansion, classified in class 204, subclass 450.
  - II. Claims 18-22, are drawn to kits, probes, primers, classified in class 536, subclass 24.3.
  - III. Claims 23-25, are drawn to non-human transgenic eukaryote utilizing a knock-out model, classified in class 800, subclass 13.
  - IV. Claims 26-28, are drawn to non-human transgenic eukaryote utilizing an over-expression model, classified in class 800, subclass 13.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP §806.05(h)). In the instant case Group I is drawn to methods of DNA expansion by using PCR amplification. The product as claimed in Group II contains oligonucleotides which can be used in materially different processes such as hybridization and array technologies.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions Group I is drawn to methods of DNA expansion by using PCR amplification. Group III is drawn to a non-human transgenic eukaryote, utilizing spliced DNA formed from two or more different sources that have been cleaved by restriction enzymes and joined by ligases, to produce a knock-out model for transgenic research protocols.

Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different structures, different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions Group I is drawn to methods of DNA expansion by using PCR amplification. Group IV is drawn to a non-human transgenic eukaryote, utilizing spliced DNA formed from two or more different sources that have been cleaved by restriction enzymes and joined by ligases, to produce an over-expression model for transgenic research protocols.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Group II is drawn to a kit containing oligonucleotides which can be used in hybridization and array technologies. Group III is drawn to a non-human transgenic eukaryote, utilizing spliced DNA formed from two or more different sources that have been cleaved by restriction enzymes and joined by ligases, to produce a knock-out model for transgenic research protocols.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different structures, different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions Group III is drawn to a non-human transgenic eukaryote utilizing a knock-out model for transgenic research protocols. Group IV is drawn to a non-human transgenic eukaryote utilizing an over-expression model.

Because these inventions are distinct for the reasons given above and the search required for each group is not required for the other groups, restriction for examination purposes as indicated is proper.

During a telephone conversation with Ms. Melissa L. Sistrunk on 6/20/02 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-17. Affirmation of this election must be made by applicant in replying to this Office action. Claims 18-28 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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- A) The phrase "gene locus associated with spinocerebellar ataxia type 10" in claim 1 renders claims 1-17 indefinite. It is unclear as to which sequence would define this locus. The metes and bounds of the scope are vague. The claim must be amended to include a SEQ ID NO.
- B) The phrase "a probe to the *SCA10* locus" renders claim 6 indefinite. It is unclear as to which sequence would define this locus. The metes and bounds of the scope are vague. It is recommended to insert a SEQ ID NO.
- C) The phrase "primer are of the sequence of..." renders claims 5, 8, 14, 16 & 17 indefinite. It is unclear as to which other sequences can be used for the primer sequence. The metes and bound of the scope are vague. The claims should be rewritten to include the following claim language: "the primers are of the sequence **consisting of** SEQ ID NO..."

#### SUMMARY

4. No claims allowed. Claims 1-17 are rejected under 35 U.S.C. 112 2<sup>nd</sup> but are free of the prior art. There is no prior art that teaches or suggests a method for detecting spinocerebellar ataxia type 10 utilizing pentanucleotide repeats and primers having the sequences consisting of SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 10, SEQ ID NO: 11. The closest prior art is Kakizuka (US 5,840,491 November 24, 1998). Kakizuka teaches a method by which a nucleotide sequence, specifically a CAG triplet repeat shown to be expanded in individuals with Machado-Joseph Disease can be identified in a sample obtainable from an individual. Kakizuka teaches PCR techniques that can be used to determine whether a CAG repeat is expanded in an individual. Kakizuka does not teach detecting pentanucleotide repeats in spinocerebellar ataxia type 10. Kakizuka does not teach a method of detecting SCA10

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comprise of determining DNA expansion by extracting DNA, amplifying the extracted DNA, and identifying the presence of DNA expansion. Kakizuka does not teach primers consisting of the previously mentioned sequences.

### CONCLUSION

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shar Hashemi whose telephone number is (703) 305-4840 and whose e-mail address is [shar.hashemi@uspto.gov](mailto:shar.hashemi@uspto.gov). However, the Office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can be best reached on weekdays from 7:00 a.m. to 3:30 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist for Technology Center 1600 whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-1235 and Before Final FAX (703) 872-9306 or After Final FAX (703) 308-9307.

*Jeffrey Siew*  
JEFFREY SIEW  
PRIMARY EXAMINER  
6/30/02